IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/579,014	Confirmation No:	5259
Applicant :	Jesse J. Kuhns et al.	Filed :	May 8, 2006
TC/A.U.:	3734	Examiner :	Katherine M. Dowe
Docket No.:	END5188USPCT	Customer No.:	000027777

Title : **DIAGNOSTIC DEVICE**

I certify this correspondence is being submitted to the USPTO via ***efs-web*** on February 17, 2012.
/Kimberly Moses/
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Submitted ***eFS-Web***
Commissioner of Patents
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Response to Final Office Action

Dear Sir:

In response to the Final Office Action Dated December 9, 2011 please amend the above-identified application as follows:

Amendments to the Claims begins on page **2** of this paper.

Remarks/Arguments begin on page **7** of this paper.

In the CLAIMS:

1. (Currently Amended) A diagnostic device for pathologies of naturally occurring tubular anatomical structures comprising:

a tubular elongated structure developing between a proximal end and a distal end and being adapted to be inserted in the tubular anatomical structure,

wherein said elongated structure comprises an inner tube and an outer tube adapted to internally receive said inner tube,

means for locally dilating the walls of the tubular anatomical structure being associated with the distal end of said elongated structure, said means for locally dilating being movable between a closed position~~, wherein the petals overlap each other,~~ for the introduction of the device and at least one open position for the viewing and evaluation of the pathology,

wherein said means for locally dilating comprise petals being arranged such that one first end thereof is associated to the distal end of the elongated tubular structure, said petals being adapted to assume at least one closed configuration and one open configuration,

said inner tube and said outer tube being suitable to translate relatively to each other to open or close said petals,

control means being associated to the proximal end of the elongated structure, said control means being operatively connected to said means for locally dilating in order to move them between the closed position and the open position, and vice versa,

in which in the region of the petals the outer tube extends distally to form said petals and a flexure hinge at said first end of the petals, ~~are formed as one piece with said outer tube~~ in which the outer tube and the petals form together one continuous external surface, and each of said petals is coupled with a portion of said inner tube forming a unidirectional guide adapted to close or open the petals in response to the translation of the inner tube relative to the outer tube and the petals.

2. (Original) The diagnostic device according to claim 1, further comprising means of viewing adapted to be associated with the elongated tubular structure and reach the tract of the tubular anatomical structure dilated by the means of dilating.

3. (Original) The diagnostic device according to claim 2, wherein the elongated tubular structure is internally hollow in order to receive the means of viewing.

4. (Cancelled)

5. (Cancelled)

6. (Cancelled)

7. (Cancelled)

8. (Previously Amended) The diagnostic device according to the claim 1, wherein one of the petals comprises at least one detection element or marker.

9. (Previously Amended) The diagnostic device according to claim 1, further comprising a membrane being externally arranged on the petals.

10. (Previously Amended) The diagnostic device according to claim 9, wherein said membrane is made in an elastic material.

11. (Previously Amended) The diagnostic device according to claim 9, wherein said membrane is made in a transparent material.

12. (Cancelled)

13. (Previously Amended) The diagnostic device according to claim 1, wherein an outer surface of the outer tube comprises at least one detection element or marker.

14. (Cancelled)

15. (Cancelled)

16. (Cancelled)

17. (Cancelled)

18. (Cancelled)

19. (Cancelled)

20. (Cancelled)

21. (Cancelled)

22. (Previously Amended) The diagnostic device according to claim 1, wherein each petal comprises a longitudinally extending rib and wherein said inner tube comprises a distal flange provided with openings adapted to couple with respective ribs of said petals.

23. (Currently Amended) The diagnostic device according to claim 22, wherein said rib has a T-shaped cross-section and wherein said openings ha~~s~~ve a C-shaped cross-section suitable to couple with the cross-section of a respective rib.

24. (Previously Amended) The diagnostic device according to one of claim 1 , wherein said inner tube comprises a holding body arranged at a proximal end of the inner tube and wherein said outer tube comprises a further holding body being arranged at a proximal end of the outer tube.

25. (Cancelled)

26. (Cancelled)

27. (Cancelled)

28. (Cancelled)

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61. (Cancelled)

62. (Cancelled)

63. (Cancelled)

64. (Cancelled)

REMARKS

Claims 59-65 have been cancelled in order to simplify prosecution. In claim 1, line 9, the limitation "wherein the petals overlap each other" has been deleted. The limitation "petals" is now correctly introduced on line 11 of claim 1. Claim 23 has been amended to correct grammar. Accordingly, no new matter is involved.

Claim 1 has been amended and recite the additional limitation that *"in the region of the petals the outer tube extends distally to form said petals and a flexure hinge at said first end of the petals, in which the outer tube and the petals form together one continuous external surface*".
Support for the amendments can be found in par[00158] and figures 19, 20, 21.

No new matter is involved.

ARGUMENTS

Withdrawal by the examiner of the double patenting rejection against the present application with respect to US appl. N. 11/662,032 is acknowledged.

In the previous office action, the Examiner objected to claims 25-31/59-65. As noted above, claims 59-65 have been cancelled. Therefore, it is respectfully requested that the Examiner withdraw this objection.

Claim 1 as amended recites that the *outer tube extends to form the petals and a flexure hinge at the first end of the petals, and the outer tube and the petals form together one continuous external surface*.
Thus, a non-traumatic continuously smooth transition from the elongated structure (outer tube) to the petals is provided and multiple-component hinges with pins are eliminated. This eliminates the risk of damage to the surrounding bodily tissue and, at the same time, reduces the number of individual pieces which need to be assembled.
Hence, the claimed invention combines non-invasiveness with a simplified and more reliable construction of the device.

Ewerhardt (US 1,950,788) discloses (fig.1, page 1, lines 92 – 100) hinges 11 secured to the cylinder 10 … One part of the hinges may be integral with the cylinder 10 and the other integral with the wing 12, when desired. However, Ewerhardt fails to disclose *the outer tube extends to form the petals and a flexure hinge at the first end of the petals, and the outer tube and the petals form together one continuous external surface.*

Pena (US 5,178,133) discloses that (figs.3,4, column 4, lines 3 to 7) operating arms 12 at said one end of support tube 11 are pivotally supported thereon by pivot pins 28. However, Pena fails to disclose *the outer tube extends to form the petals and a flexure hinge at the first end of the petals, and the outer tube and the petals form together one continuous external surface.*

Wallace (US 2,621,651) discloses an instrument for dilating and examining the esophagus in which (col. 3, lines 45-48, col. 4, lines 36-40) each dilator member 35 is connected to a free end of a corresponding flexible arm 33, 133 by a rivet 36 and is pivoted to an inner tube by pins 37, 137. However, also Wallace fails to disclose *the outer tube extends to form the petals and a flexure hinge at the first end of the petals, and the outer tube and the petals form together one continuous external surface.*

Sijp (DE19828099) discloses a rectoscope in which pin-hinges 4 connect lamellae 3 to a connecting element 8 and the connecting element 8 movably connects the bushing 1 with the pushing element 9 (col. 3, lines 12 - 15. However, Sijp fails to disclose *the outer tube extends to form the petals and a flexure hinge at the first end of the petals, and the outer tube and the petals form together one continuous external surface.*

Yoon (US5,556,376) discloses a multifunctional device with a collection system 62 (Figs. 6,7, col. 10, lines 29-31) in which a collection bag 72 is attached to an inner member 70. However, Yoons fails to disclose *the outer tube extends to form the petals and a flexure hinge at the first end of the petals, and the outer tube and the petals form together one continuous external surface.*

It is respectfully requested that the Examiner withdraw the rejection to claim 1. In addition, because all other claims depend from claim 1, Applicants respectfully request that the Examiner withdraw the rejections to these claims as well.

Therefore, Applicants respectfully request that the Examiner re-examine and favorably reconsider Applicants' claims in the form of a Notice of Allowance.

Respectfully submitted,

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